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11-29-2000

Mary S. Wolfe, Ph.D.  
Executive Secretary, National Toxicology Program  
P.O. Box 12233, A3-07  
Research Triangle park, NC 27709

Re: 10<sup>th</sup> ROC Nominations: solicitation of Public Comment- "Talc Containing Asbestiform Fibers"

Dear Dr. Wolfe:

In response to the captioned call for public comment, I am enclosing written comments. It is intended that this submission be considered by the NTP Board of Scientific Counselors' Subcommittee prior to the scheduled meeting of the Subcommittee on Dec 13-15, 2000. The comments are based on the results of my review of medical surveillance examinations performed every two years on the workers at the Gouverneur Talc Company. I am familiar with the examinations having acted as an advisor to the Corporate Manager of Occupational Safety and Health for the R. T. Vanderbilt Company (operator of the talc mining and milling facility) and having personally reviewed the radiographs. The views are my own and are not to be construed as official comments by the University of North Carolina at Chapel Hill.

Respectfully submitted,

A handwritten signature in cursive script that reads "Brian Boehlecke".

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11-29-2000

Submission to the NTP regarding the 10<sup>th</sup> ROC Nominations: solicitations of Public Comment- "Talc Containing Asbestiform Fibers"

Brian Boehlecke MD, MSPH

These comments are based on my review of the results of medical surveillance examinations performed every 2 years on workers at the Gouverneur Talc Company. I enclose comments relevant to this solicitation which were previously submitted to the OSHA Docket H-033-d in 1990 as well as an update including the results of the examinations conducted in 2000.

I have continued to serve as an advisor to the Corporate Manager of Occupational Safety and Health of the R.T. Vanderbilt Company since the submission of comments to OSHA in 1990. I have thereby personally reviewed the chest radiographs of the workers at Gouverneur Talc company taken during each subsequent round of medical surveillance examinations.

In 2000, I reviewed the chest radiographs of 115 workers with exposure to the talc mined and milled at Gouverneur Talc Company. Findings were as follows.

Ten workers had findings which could be related to occupational exposure to talc. Six had definite pleural plaques and 2 had possible pleural plaques, all of which had been present on previous examinations and did not show progression. The length of time from first exposure to talc at Gouverneur Talc Company ranged from 21 to 35 years.

One man had possible irregular opacities (ILO Classification of profusion of 1/0) which had shown no change since 1994. He has had 31 years of exposure.

No evidence of lesions consistent with a malignancy was observed by myself or by the radiologist who performed the clinical readings of these films.

One man had a radiograph finding consistent with new pleural plaques. He had 26 years of exposure. Further medical evaluation of these findings by the worker's private physician has been performed. I have not seen the results of this evaluation but have been informed that nothing of clinical significance was found.

My interpretation of these findings is that the workers exposed to talc mined and milled at the Gouverneur Talc Company do have a risk for development of benign focal pleural thickening (pleural plaques) as has been demonstrated to exist for exposure to talc which has no associated "asbestiform fibers". The risk of development of plaques has been demonstrated to be related to the latency since first exposure and the men in this workforce with plaques have all had over 20 years since first exposure.

Only one man had any evidence of increased interstitial markings which could be consistent with a pneumoconiosis. These markings have not increased in profusion in the past 6 years despite continued exposure.

The medical surveillance results from workers at Gouverneur Talc Company available to me at this time continue to support the conclusion submitted to the OSHA docket in the 1990, i.e. the data do not indicate that the workers exposed to the talc at this facility are at risk for developing asbestos related pneumoconiosis. They do appear at risk for developing conditions shown to develop in workers exposed to talc not containing asbestos. With current occupational exposure levels, essentially no progression of pneumoconiosis related to cumulative exposure appears to have occurred in the men in this workforce for whom I have had serial radiographs to review.

BBoehlke MD, MSPH

April 23, 1990

Submission to OSHA Docket H-033-d  
from BRIAN BOEHLECKE, M.D., M.S.P.H.

*B. Boehlecke MD, MSPH*

These comments are based on the results of my review of medical examinations performed on workers at the Gouverneur Talc Company (GTC) as part of the company's medical surveillance program and on my interpretation of pertinent medical literature.

In 1985 I reviewed the chest radiographs of 203 current workers at GTC who had been examined in 1984. I also tabulated the interpretations of the radiographs taken in 1982 which had been read previously by 2 other NIOSH certified "B" readers. Abnormalities were considered to be definitely present when at least 2 of the three readings agreed on the presence of the condition. For all workers whose 1982/1984 radiograph(s) showed an abnormality which might be consistent with a pneumoconiosis, I later reviewed all radiographs in the worker's file to determine when the abnormality was first detectable. The Company also abstracted each worker's occupational history from his employment application to determine whether any exposure to talc or other minerals may have occurred prior to hire at GTC. Results of the review of previous radiographs and work history are given in Table 1.

#### Parenchymal Opacities

There were 3 workers whose 1982/1984 radiograph(s) showed parenchymal changes consistent with pneumoconiosis (irregular linear opacities).

All 3 men with parenchymal opacities had had 10 or more years of occupational exposure to N.Y. State talc at other facilities before working at GTC. In all cases radiographic abnormalities were first detectable within 3 years of starting at GTC. For worker #110 the parenchymal opacities were definitely present on a film taken 3 years after hire (category 1/0) and were probably present on his initial radiograph at GTC which I interpreted as category 0/1. For workers #131 and #2002 the opacities were present on the first film taken after hire at GTC.

One additional worker had a question of parenchymal opacities on his 1984 film but the 1982 film was read as negative by both readers. Review of his 1978 film upon hire at GTC showed the same questionable appearance of opacities which had not changed on subsequent films. He is not shown on Table 1.

### Localized Pleural Thickening (Plaques)

The consensus radiographic review identified seven other cases with only localized pleural thickening (plaques). Unlike cases with parenchymal changes, only one of these 7 men had reported previous occupational exposure to N.Y. State talc. The pleural changes were present on his film at the time of hiring at GTC. The onset of recognizable pleural thickening ranged from 7 to 23 years after hire in the men without previous exposure to talc.

One additional case of possible pleural thickening was reviewed although there was no consensus on the 1982/1984 films. By viewing previous films I concluded he probably did have a pleural plaque on his hemidiaphragm which was first detectable 20 years after hiring at GTC. He had 13 years of occupational exposure to N.Y. State Talc prior to working at GTC but is not shown on Table I since there was not a consensus about the findings.

### Follow-up

I have continued to review the radiographs of the workers at GTC on subsequent rounds of medical surveillance examinations done each 2 years. None of the men with abnormalities described above have shown significant radiographic progression since the 1984 examination.

In early April 1990 I reviewed the current radiographs of 55 men who have worked 15 or more years at GTC in jobs with potential exposure to talc and who had no other reported occupational exposure to talc. Four of these men (7.3%) had definite pleural plaques and 2 (3.6%) had probable pleural plaques. None had definite parenchymal opacities consistent with a pneumoconiosis. The years of exposure were 16, 25, 31, and 40 for the men with definite plaques and 20 and 24 for those with probable plaques.

### Interpretation

My interpretation of these observations is as follows:

1. The parenchymal opacities detected to date appear to be associated with exposures prior to working at GTC. They were detectable within 3 years or less of beginning work at GTC which would be a very short latency unless exposures were very high. This seems unlikely since employees without prior exposure have not demonstrated similar onset. All three men had had 10 or more years of previous exposure which would be sufficient time for the onset of a pneumoconiosis which would become clinically manifest thereafter.
2. There is no evidence from these data that additional cases of parenchymal pneumoconiosis are developing in the GTC workforce under current conditions or that significant progression of previously detected cases is occurring.

3. The medical surveillance examinations should be continued to monitor the workforce for possible new cases or progression of established cases.
4. Some men appear to have developed pleural plaques in association with occupational exposure at GTC without recognized exposure to other N.Y. State talc. This is evidenced by the review of the 1982/1984 radiographs and those of the current workers with 15 or more years work at GTC.

### Discussion

The finding of an association between plaques and occupational exposure to this talc does not necessarily imply that the talc must be contaminated with asbestos. In some population surveys, only a minority of persons with pleural plaques had recognizable exposure to asbestos (1-3). Occupational exposures to other talcs which were not associated with any asbestiform minerals have also been associated with a prevalence of pleural plaques higher than that found in a control population. Importantly, the prevalence of plaques in the workers exposed to these nonamphibole containing talcs was similar to that found at GTC.(4).

Moreover, the finding of pleural plaques does not by itself imply that the work environment carries the same risk for other adverse health effects associated with exposure to asbestos. Pleural plaques are not premalignant lesions and are generally not considered to be markers of an increased risk for malignancy beyond that which would have been associated with a given exposure in the absence of the development of plaques (5-7). Workers with occupational exposure to asbestos and radiographically detected pleural plaques have not been shown to have an increased risk of developing bronchogenic carcinoma relative to that of workers with similar exposure to asbestos but no plaques (8). Also, plaques are not uniformly associated with pulmonary parenchymal fibrosis (5). Even on careful pathologic examination, only a minority of persons with pleural plaques showed interstitial fibrosis; the proportion with fibrosis was not different from that in matched controls without plaques (9). Therefore, the presence of plaques alone does not necessarily imply the presence of the risks which are associated with exposure to asbestos.

Nevertheless, the risk of development of a parenchymal pneumoconiosis ("talcosis") has long been recognized to be associated with over exposure to airborne talc. I believe that the Gouverneur Talc Company recognizes this risk and has informed its employees and customers of it.

Previous studies of N.Y. State talc miners showed that excess non-malignant respiratory disease occurred in association with the very high dust levels present before modern dust control methods were implemented. The presence of parenchymal opacities on chest

radiographs taken shortly after hire at GTC in men with prior exposure to talc is consistent with this observation. However, the radiographic reviews described here suggest that the risk is much less for workers exposed to current conditions at GTC.

### Conclusion

Current employees at Gouverneur Talc Company do not appear to have the same risk for pneumoconiosis as was present for men with exposure to the much dustier work environments of the past. Adequate medical surveillance and dust control are still vital to the health of the workforce and are continuing. Characterization of the radiographic findings in GTC workers as indicative of "asbestos related diseases" (OSHA proposed rule page 4947, paragraph 8) with the implication of the presence of excessive risk of adverse health effects under current conditions is not supported by the data presented here.

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## References

1. Albelda, S.M., Epstein, D.M., Geffer, W.B., and Miller, W.T. Pleural Thickening: Its Significance and Relationship to Asbestos Dust Exposure. *Am. Rev. Respir. Dis.* 1982; 126:621-624.
2. British Thoracic & Tuberculosis Association & Medical Research Council Pneumoconiosis Unit. A Survey of Pleural Thickening: Its Relation to Asbestos EXposure & Previous Disease. *Environ. Res.* 1972; 5:142-151.
3. Rous, V. and Studeny, J. Aetiology of Pleural Plaques. *Thorax* 1970; 25:270-84.
4. Gamble, J., Greife, A., Hancock, J. An Epidemiological-industrial Hygiene Study of Talc Workers. *Ann. Occup. Hyg.* 1982; 26:841-859.
5. Rubin, A-HE. Common Problems in Asbestos-Related Pulmonary Diseases. *Am. J. Ind. Med.* 1986;10:555-562.
6. Edelman, D.A. Asbestos Exposure, Pleural Plaques and the Risk of Lung Cancer. *Int. Arch. Occup. Environ. Health.* 1988; 60:389-393.
7. Weil, H. Asbestos-associated Diseases. Science, Public Policy, and Litigation. *Chest* 1983; 84(5): 601-608.
8. Harber P., Mohsenifar, A., Oren, A., and Lew, M. Pleural Plaques and Asbestos-Associated Malignancy. *J. Occup. Med.* 1987; 29(8): 641-644.
9. Sison, R.F., Hruban, R.H., Moore, G.W, Kuhlman, J.E., Wheeler, P.S., and Hutchins, G.M. Pulmonary Disease Associated with Pleural "Asbestos" Plaques. *Chest* 1989; 95(4): 831-835.



Table 1

Workers with abnormalities consistent with penumoconiosis in 1982/1984

Worker #	Radiographic Abnormality in 1982/1984	Years* of talc exposure prior to hire at GTC	Years from hire at GTC to first evidence of the radiographic abnormality
1.	110 parenchymal, pleural	10-12	0-3
2.	131 parenchymal, pleural	12-14	1
3.	2002 parenchymal, pleural	10-12 +10 chemical co	2
4.	392 pleural only	none	7
5.	263 pleural only	none	20
6.	56 pleural only	none	12
7.	231 pleural only	none	12
8.	85 pleural only	none	20
9.	111 pleural only	none	23
10.	1655 pleural only	13-15	0

\*The range of years is given because the exact portion of the years worked for the first and last years of previous employment was not available.

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SUPPORT DOCUMENTS AND  
TESTIMONY REFERENCES

1. Curriculum Vitae
2. Boehlecke, B. correspondence to R.T. Vanderbilt Company regarding radiographic interpretations and recommended follow-up. October 21, 1985 (case names deleted)
3. Listing of Abnormal Radiographs (any reason): Employees as of 1984: Historical Review
4. Boehlecke, B. correspondence to R.T. Vanderbilt Company regarding radiographic interpretations and recommended follow-up. Aug. 10, 1988 (case names deleted)
5. Gamble, J., et al., "An Epidemiological-Industrial Hygiene Study of Talc Workers," Am. Occup. Hyg. Vol. 26, Nos. 1-4, pp. 841-859, 1982, Text Ref. #4
6. Sison, R.F., et al., "Pulmonary Disease Associated with Pleural Asbestos Plaques" Chest/94/4/ (April 1989), pp. 831-835
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8. Edelman, D., "Asbestos Exposure, Pleural Plaques and the Risk of Lung Cancer," Int. Arch. Occup. Envir. Health. 60 (1988), pp. 389-393, Tex. Ref. #6
9. Parker, D.L., et al., "Public Health Implications of the Variability in the Interpretation of "B" Readings for Pleural Changes," J. Occup. Med. Vol. 31, No. 9 (Sept. 1989), pp. 775-780

NOTE: additional references cited in the testimony text not attached.